HFD-613/OGD

NDA 20-470/S-005

DEC 4 1998

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Joseph F. Lamendola, Ph.D.
Vice President
US Regulatory Affairs

Dear Dr. Lamendola:

Please refer to your supplemental new drug application dated March 4, 1998, received March 5, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claritin-D 24 Hour (10 mg loratadine/240 mg pseudoephedrine sulfate, USP) Extended Release Tablets.

We acknowledge receipt of your submissions dated May 26, July 2 and 13, August 24 and 26, October 23, November 5 and 23, and December 3,1998.

This supplemental new drug application provides for a reformulated tablet with a new shape and coating.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted draft labeling. Accordingly, the supplemental applicationis approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted December 3,1998, immediate container and carton labels submitted March 4, 1998).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-470/S-005." Approval of this submission by FDA is not required before the labeling is used. We remind you of your agreement to revise the carton and container labels to read "Take with a full glass of water" in place of the current "Take with a glass of water" within three months of the date of this letter.

We remind you of your Phase 4 commitments specified in your submission dated December 3, 1998. These commitments, along with any completion dates agreed upon, are listed below.

1. You will conduct a single-dose, 5-way cross-over bioavailability study with the reformulated Claritin-D 24 Hour product, Claritin-D 12 Hour,, Claritin Tablets, Claritin RediTabs, and Claritin Syrup in adults. A second single-dose, two-way, within-batch, replicate, cross-over study will be conducted with Claritin Syrup in adults. The protocols for these studies will be sent to the FDA within 30 days of the date of this letter. You will initiate the studies within two months of the date of this letter, and submit the study reports within eight months of the date of this letter.

2. You will initiate a prospective active surveillance program as outlined in your December 3, 1998, letter. The protocol for this surveillance effort should be submitted to the FDA within 30 days of the date of this letter, and the study will be initiated within two months of the date of this letter.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. In addition, under 21 CFR 3 14.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated “Phase 4 Commitments.”

In addition we remind you of the following agreements.

1. You will replace/exchange all existing Claritin-D 24 Hour marketed product to the pharmacy level within 14 days of the date of this letter.

2. You will submit a prior-approval supplement for any extension of the 18-month expiration dating period according to the approved stability protocol.

3. Within six months of the date of this letter you will develop and submit, as a changes-being-effected supplement, a new test method which will meet the appropriate specifications according to ICH guidelines for unspecified and total impurities.

4. You will initiate mailing of the “Important Prescribing Information” correspondence as included in the December 3, 1998, submission no later than December 11, 1998.

5. You will issue the press release included in the December 3, 1998, submission no later than Monday, December 7, 1998.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We request that a copy of your letter communicating important information about this drug product (i.e., the "Dear Health Care Practitioner" letter) be submitted to the NDA, and a copy be submitted to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Mrs. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely yours,

John K. Jenkins, M.D., F.C.C.P.
Director
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research